AIDS Research Advisory Committee

Guiding Principles for DAIDS Clinical Research Networks

January 26, 2004

Timetable for FY06 Clinical Research Networks

• September 2001	Ongoing consultations
• January 2004	ARAC review draft concepts
• May 2004	ARAC review final concepts
• Fall 2004	Release of solicitations
• Fall 2004	Pre-application meetings
• Spring 2005	Receipt of applications
• Summer 2005	Review of applications
• FY 06	Awards

Consultations/Discussions to Date

- October 2001: 1st Network Leaders Meeting.
  Focus: Integrating Prevention & Treatment Research; Initiate HPTN 052/AACTG 5175 collaboration
- November 2002: AACTG & HPTN Chairs.
  Focus: HPTN 052/AACTG 5175 coordination
- June 2003: 2nd Network Leaders Meeting.
  Focus: Structuring the Clinical Research Effort
- September 2003: 3rd Network Leaders Meeting.
  Focus: Integrating Prevention & Treatment Research
- September 2003: ARAC Meeting.
  Discussion: “Developing a Model for Clinical Research Networks in a Global Environment”

Consultations/Discussions (cont.)

- December 2003: 3rd Network Leaders Meeting. Focus: Inter-network coordination & integration plan;
- December 2003: AACTG Executive Committee and Principal Investigators;
- December 2003: HIV/AIDS Community-based organizations/constituencies
- February 2004: HVTN, HPTN & ESPRIT Executive Committees and Principal Investigators
- March 2004: Office of AIDS Research led meetings with NIH IC HIV/AIDS Coordinators & program leadership
- April 2004: CPCRA and PACTG Executive Committees and Principal Investigators

What we've learned so far

Strengths of networks

- Bring together expert investigators in collaborative groups
- Peer-review hones ideas & improves research quality
- Provide continuity for strategic planning and product development
- "Re-usable" infrastructure promotes efficiency, data quality & comparability

What we've learned so far

Shortcomings of networks

- Protocol development can be slow
- Time commitment can be huge
- Can be overly risk averse or dogmatic
- Leadership can be seen or function as closed shops
- Can put up walls & function in isolation from one another

What are the options?

Tear them down and start over?

Starting from scratch

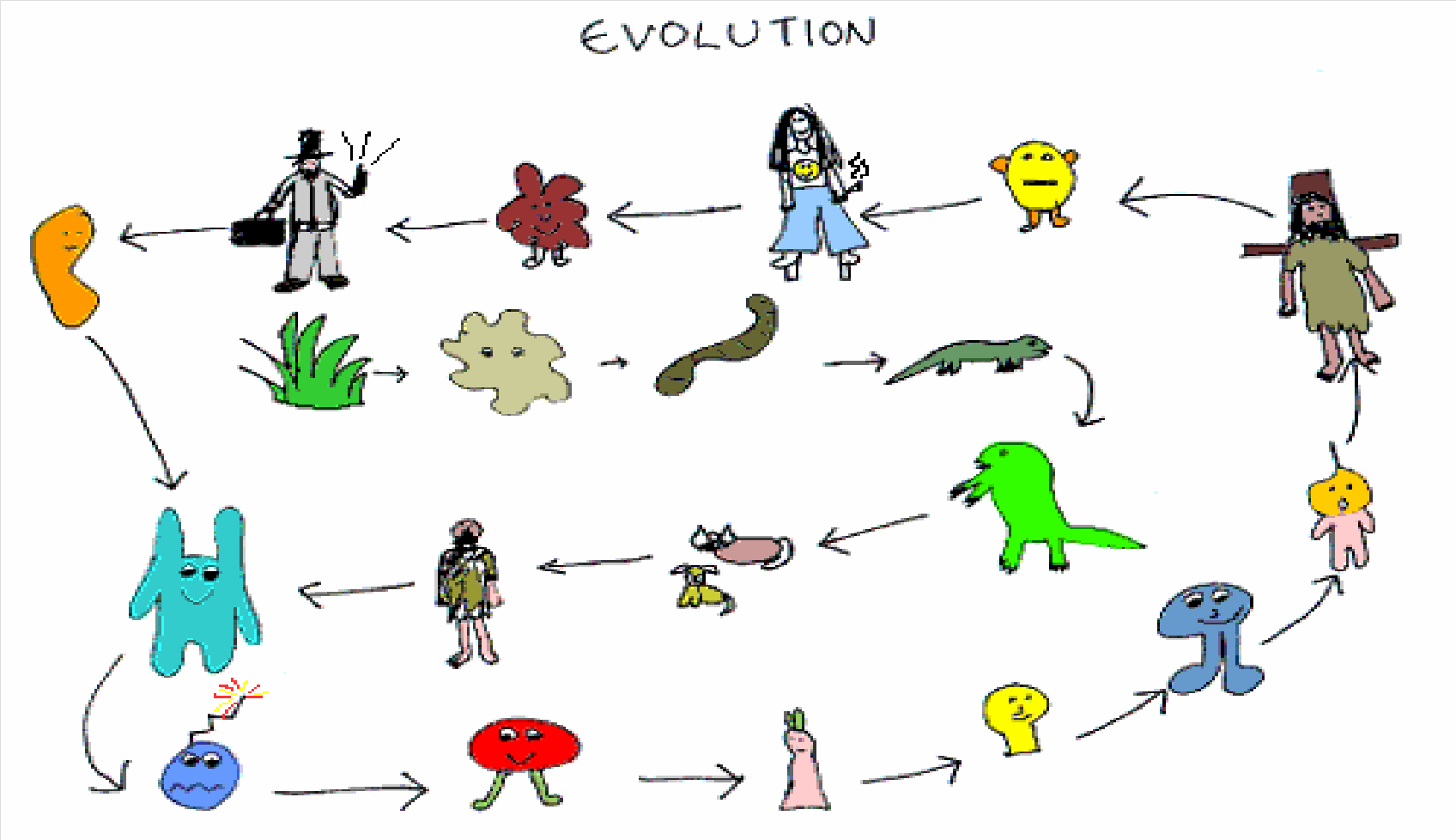
Pros:

- Rebuild from ground up based on lessons learned
- Break the ‘status quo’; greater chance for ‘out of box’ thinking

Cons:

- Significant disruption; wastes precious time and resoures
- May throw the baby out with the bathwater

…or evolve ?



…to ‘better fit’ a new environment

Ch-ch-ch-ch Changes:

- Scientific priorities
- Populations and demographics (US and abroad)
- Partners
- Oversight/regulatory bodies
- Fiscal constraints

Which way to go?

Input to-date from advisory groups, consultations with community-based organizations, investigators & DAIDS staff:

To evolve and adapt is better than to start over; keep the research moving forward but manage it and coordinate it better for improved science & greater efficiency

Guiding Principles for Evolving the Networks

- Address domestic and international clinical research questions of highest priority
- Integrate HIV/AIDS prevention and treatment research for the best clinical science
- Maximize scientific opportunities through coordinated research
- Increase efficiency through resource sharing
- Build and sustain clinical research capacity in resource poor settings
- Partner with organizations with complementary strengths

Putting principles into action

- Cross-Group leadership, increased accountability & greater scientific coordination
- Coordinated development of pluripotent international clinical research sites
- Sharing of laboratory resources and protocols
- Common data entry interfaces and data elements
- Coordinated specimen management guidelines
- Shared/standardized training for common needs
- Meet with one another!
- Coordinated approach to clinical research product acquisition, distribution and provision
- Become more efficient with all resources, including $$

Leadership & Coordination

- Network Leaders:
  - Increased accountability to DAIDS/NIAID
  - Greater responsibility for performance of all network components (e.g. Operations, Laboratories, Data Centers)
  - Coordinate scientific agenda and research with other efforts
  - Integrate with other efforts as appropriate
  - Exercise increased flexibility to better manage resources

Clinical Research Sites

- Domestic sites
  - Fuel domestic agenda & enhance international efforts
  - Possibly become “center”-like, depending on expertise/interest
- International sites:
  - Foster contributions to prevention & therapeutic research
  - Evolve to “pluripotency”
- All sites
  - Core funding from NIAID (cooperative agreement) supplemented through Networks based on performance and need

Laboratories

- Coordinate/integrate laboratories for increased scientific data comparability and efficiency
  - Locations, infrastructure, data management, QA/QC, training/support
  - Regional laboratories to support multiple networks
- Core laboratories (e.g. CD4, viral load, safety) supported by DAIDS
- Specialized laboratories (e.g. endpoints) supported and overseen by the networks

Data Management & Operations Centers

- Increase access to scientific and administrative data for cross-protocol and cross-network analysis
  - Collaborate for greater efficiency
  - Establish standard data interfaces
  - Standardize common data elements, protocol status definitions, endpoint verification, formats for data collection, site name/numbering, protocol templates…
  - Interface with DAIDS-Enterprise Information System
- Accountable to networks

Specimen Management

- Acquisition, processing & storage
- Shipping/tracking
- DNA/genetic material (policy, international negotiation)
- Repositories (including international issues)
- Retrieval & QA/QC
- Sample disposition

Training

- Coordinated/shared training
  - Site establishment/site initiation
  - Project management; fiscal management
  - Biostatistics; Data management
  - GCP/GLP
  - Regulatory compliance (in-country, US, etc)
  - Safety reporting
  - Biomedical research ethics, human subjects, informed consent
  - Regional training programs
- Network-specific training
  - Peer-to-peer scientific collaboration
  - Protocol-specific training

Cross-Network Meetings

- Development of coordinated scientific research agendas
- Planning and management of shared resources
- Learning from each others' strengths
- Coordinate interactions with shared clinical research sites
- Less time in airports

Clinical Research Product Acquisition, Distribution & Provision

- Coordinated approaches to accessing ARVs, vaccines/immunogens, etc.
- Leveraging the collective strength of networks
- Potential to develop regional product distribution
- Coordinate plans for post-trial access to & provision of therapy

HIV CLINICAL RESEARCH MANAGEMENT SUPPORT CONTRACT

- Enhance research program capacity:
  - Close coordination with investigators & network leadership to define needs & coordinate roles
  - Site assessment, planning, management
  - On-site recruitment, training, staffing
  - Address unique needs of institutions/regions
  - Sustained presence for long-term development

Non-network clinical research

- NIAID will continue to support HIV clinical research outside of network structures
- A new funding mechanism will help to ensure:
  - Scientific relevance/contextual prioritization
  - Operational feasibility and quality
- Potential access to DAIDS network resources depending on scientific priority and relevance